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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,801	07/06/2001	Richard Eustis Fulton III	ARTM 1000-5US	6827

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EXAMINER
SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

SM

	Application No.	Applicant(s)	
Office Action Summary	09/900,801	FULTON ET AL.	
	Examiner	**Art Unit**	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89-160* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-160* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,8,9* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

Claim Objections

1. Claim 157 is objected to because of the following informalities: "visulizable" should be written as "visualizable" in line 2 of the claim. Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 89 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 19 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claim.

4. Claims 91, 93 and 105-107 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the issued claim is written in a broader language than the current claims.

5. Claim 90 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claim.

6. Claims 94, 97-100, 102, 103, 108, 111-114, 116 and 117 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12, 13, 19, 22, 21, 3 and 6 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

7. Claim 104 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 10 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claim.

8. Claim 92 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 11 and 19 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claim.

9. Claims 118, 127 and 136 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26, 30 and 40 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

10. Claims 119-124, 128-133 and 137-142 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 27, 29, 31, 39, 42 and 43 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

11. Claims 126, 135, 146, 148, 152 and 160 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claims.

12. Claim 125 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the used claim.

13. Claims 134 and 143 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of U.S. Patent

No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language then the current claim.

14. Claims 144 and 145 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26 and 27 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

15. Claims 147 and 154 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claim.

16. Claim 150 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 40 of U.S. Patent No. 6,270,464 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claim is written in a broader language than the current claim.

Claim Rejections - 35 USC § 102 & 103

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 89, 102 and 103 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Haaga ('392).

Haaga discloses a biopsy system with a hemostatic insert, and further discloses a bioabsorbable element in a pre-delivery state; the bioabsorbable element is in an a post-delivery state at the target tissue site; the element is softer in the post-delivery state than in its pre-delivery state; and the element is physically different in its post-delivery state than in the pre-delivery state. See Column 1, lines 11-17; Column 3, lines 16-54; Column 4, lines 3-19 and 25-32; Column 7, lines 20-67; and Column 8, lines 1-9. Even though Haaga does not disclose the element being remotely visualizable, it would have been obvious to one of ordinary skill in the art at the time the invention was made to recognize the material the element is constructed from would inherently allow a

radiologist to locate the element in the tissue due to the different density of the element when compared to the surrounding tissue.

20. Claims 144-149, 152-157 and 160 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirimanne et al ('782).

Sirimanne et al discloses a subcutaneous cavity marking device and method, and further discloses taking tissue from the target tissue site; selecting a remotely visualizable bioabsorbable element; positioning the element at the target tissue site; at least a portion of the element is radiopaque; a biopsy is obtained at the target tissue site; the positioning is carried out using remote visualization; testing the tissue sample; if necessary, treating the target tissue; removing additional tissue at the target site if necessary; relocating the target site by finding the element; relocation is done by one of palpation and remote visualization; remote visualization is done by at least one of ultrasound, mammography and MRI; and relocation is carried out prior to the treating step. See Abstract; Column 3, lines 29-32; Column 7, lines 55-67; and Column 11, lines 22-36.

21. Claims 90, 91 and 93-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga ('392) as applied to claim 89 above, and further in view of Mavity et al.

Haaga, as discussed above, discloses a biopsy system with a hemostatic insert, but fails to disclose a therapeutic agent; a chemotherapy agent; a gene therapy agent; means for receiving a therapeutic agent; and a radiation agent.

Mavity et al disclose an absorbable brachytherapy and chemotherapeutic delivery device and method and further disclose a therapeutic agent; a chemotherapy agent; a gene therapy agent; means for receiving a therapeutic agent; and a radiation agent. See Column 4, lines 20-56; Column 6, lines 27-39; Column 8, lines 34-50; and Column 10, lines 23-28.

Since both Haaga and Mavity et al disclose the use of a bioabsorbable therapeutic element, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Haaga to include the use of therapeutic agents such as chemotherapeutic, radiation and gene therapy, as per the teachings of Mavity et al, since it would provide a means of applying a therapy directly to a target site while preventing the surrounding tissue from exposure to such agents.

22. Claims 98-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haaga ('392) as applied to claim 89 above, and further in view of Sirimanne et al ('782). Haaga, as discussed above, discloses a biopsy system with a hemostatic insert, but fails to disclose a marker element in contact with the bioabsorbable element; a radiopaque marker located generally centrally within the element; the radiopaque marker is a permanent marker; and the element is visualizable by at least one of ultrasound, mammography and MRI.

Sirimanne et al, as discussed above discloses a subcutaneous cavity marking device and method, and further discloses a marker element in contact with the bioabsorbable element; a radiopaque marker located generally centrally within the element; the radiopaque marker is a permanent marker; and the element is visualizable by at least

one of ultrasound, mammography and MRI. See Abstract; Column 3, lines 29-32; Column 7, lines 55-67; and Column 11, lines 22-36.

Since both Haaga and Sirimanne et al disclose means for applying a bioabsorbable element at a target site, it would have been obvious to one of ordinary skill in the art the time the invention was made to modify the device of Haaga to include the use of a marker, as per the teachings of Sirimanne et al, since it would provide a means of easily visualizing the element using MRI, ultrasound or radiographic means.

23. Claims 150, 151, 158 and 159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al ('782) as applied to claim 148 above, and further in view of Mavity et al.

Sirimanne et al, as discussed above discloses a subcutaneous cavity marking device and method, but fails to disclose delivering a therapeutic agent to the target site; a chemotherapy agent; activating the site; and injecting a radiation-emitting element at the site.

Mavity et al, as discussed above, disclose an absorbable brachytherapy and chemotherapeutic delivery device and method and further disclose a therapeutic agent to the target site; a chemotherapy agent; activating the site; and injecting a radiation-emitting element at the site. See Column 4, lines 20-56; Column 6, lines 27-39; Column 8, lines 34-50; and Column 10, lines 23-28.

Since both Sirimanne et al and Mavity et al disclose means for placing a bioabsorbable element at a target site, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sirimanne et al to include

placing a therapeutic agent at the target site, as per the teachings of Mavity et al, since it would provide a means of placing a therapeutic agent in the target tissue while limiting the exposure of the agents to the surrounding healthy tissue.

24. Claims 92, 104-112, 116, 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mavity et al in view of Haaga ('392).

Mavity et al, as discussed above, disclose an absorbable brachytherapy and chemotherapeutic delivery device and method, but fail to disclose a therapeutic bioabsorbable element in a pre-delivery state; the element is in a post-delivery state at the target tissue site; the element is softer in the post-delivery state than in the pre-delivery state; and the element is physically different in the post-delivery state than in the pre-delivery state.

Haaga, as discussed above, discloses a biopsy system with a hemostatic insert, and further discloses a therapeutic bioabsorbable element in a pre-delivery state; the element is in a post-delivery state at the target tissue site; the element is softer in the post-delivery state than in the pre-delivery state; and the element is physically different in the post-delivery state than in the pre-delivery state. See Column 1, lines 11-17; Column 3, lines 16-54; Column 4, lines 3-19 and 24-30; Column 7, lines 20-67; and Column 8, lines 1-9.

Since both Mavity et al and Haaga disclose means for placing a bioabsorbable therapeutic element at the target site, it would have been obvious to one of ordinary skill in the art the time the invention was made to modify the device of Mavity et al to include the changing of the shape of the element at the target site, as per the teachings of

Haaga, since it would provide a means of filling the cavity at the target site while providing a therapeutic agent to the site.

25. Claims 113-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mavity et al and Haaga ('392) as applied to claim 104 above, and further in view of Sirimanne et al ('782).

Mavity et al and Haaga, as discussed above, disclose means for applying a bioabsorbable element to a target site, but fail to disclose a radiopaque marker; the radiopaque marker is a permanent marker; and the element is remotely visualizable by at least one of ultrasound, mammography and MRI.

Sirimanne et al, as discussed above discloses a subcutaneous cavity marking device and method, and further disclose a radiopaque marker; the radiopaque marker is a permanent marker; and the element is visualizable by at least one of ultrasound, mammography and MRI. See Abstract; Column 3, lines 29-32; Column 7, lines 55-67; and Column 11, lines 22-36.

Since Mavity et al, Haaga, and Sirimanne et al disclose means for placing bioabsorbable therapeutic elements at a target site, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the devices of Mavity et al and Haaga to include a radiopaque marker, as per the teachings of Sirimanne et al, since it would provide a means of easily visualizing the element using MRI, ultrasound or radiographic means.

26. Claims 118-121, 125-130, 134-139 and 143 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al ('782) in view of Mavity et al.

Sirimanne et al, as discussed above discloses a subcutaneous cavity marking device and method, but fail to disclose using a bioabsorbable element capable of yielding therapy via delivery of a therapeutic agent to the element; and positioning the element at the tissue site.

Mavity et al, as discussed above, disclose an absorbable brachytherapy and chemotherapeutic delivery device and method, and further disclose using a bioabsorbable element capable of yielding therapy via delivery of a therapeutic agent to the element; and positioning the element at the tissue site. See Column 4, lines 20-56; Column 6, lines 27-39; Column 8, lines 34-50; and Column 10, lines 23-28.

Since both Sirimanne et al and Mavity et al disclose means for applying a bioabsorbable element to a target site, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Sirimanne et al to include the use of an element capable of applying a therapy to the tissue surrounding the target site, as per the teachings of Mavity et al, since it would provide a means of treating the tissue immediately next to the removed target tissue to prevent further growth of the tumor tissue.

27. Claims 123, 132 and 141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirimanne et al ('782) and Mavity et al as applied to claims 118, 127 and 136 above, and further in view of Haaga ('392).

Sirimanne et al and Mavity et al, as discussed above, disclose means for applying a bioabsorbable element to a target site, but fail to disclose preventing blood form contacting the element until the element is positioned at the target site.

Haaga, as discussed above, discloses a biopsy system with a hemostatic insert, and further discloses preventing blood form contacting the element until the element is positioned at the target site. See Column 4, lines 24-30.

Since Sirimanne et al, Mavity et al and Haaga disclose means for placing a bioabsorbable element at a target site, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Sirimanne et al and Mavity et al, to include the use of preventing exposure of the element until it is at the target site, as per the teachings of Haaga, since it would prevent the element from expanding prematurely within the delivery device before the element is at the target site.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737, and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.

BS
September 25, 2002

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